SECTION 5: 510(k) SUMMARY K112232

Submitter:

Stryker Sustainability Solutions
10232 South 51st Street
Phoenix, Arizona 85044

SEP 26 2011

Contact:

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Date of preparation: August 3, 2011

Name of device: *Trade/Proprietary Name:* Reprocessed Electrophysiology Catheters
Classification Name: Electrode recording catheter or electrode recording probe

Predicate Device	510(k) Title	Manufacturer
K081329	Reprocessed Electrophysiology Catheters	Ascent Healthcare Solutions
K060757	Inquiry Optima Plus Steerable Electrophysiology Catheter	Irvine Biomedical
K042775	Inquiry™ AFocus™, Inquiry™ AFocusII™, or Inquiry™ Optima™ Steerable Electrophysiology Catheter	Irvine Biomedical
K010471	Inquiry™ AFocus™ Steerable Electrophysiology Catheter	Irvine Biomedical
K990958	Orthogonal™ Steerable Electrophysiology Catheter	Irvine Biomedical
K982232	IBI-1100 Bi-directional Steerable Electrophysiology Catheter	Irvine Biomedical
K961924	IBI-1100 Steerable Electrophysiology Catheter	Irvine Biomedical
K946333	IBI-1000™ Electrophysiology Catheter	Irvine Biomedical

Device description: The Reprocessed Diagnostic Electrophysiology (EP) Catheters are specially designed electrode catheters that transmit electrical impulses and can be positioned for endocardial recording or stimulation. Diagnostic EP catheters incorporate a hand piece, a flexible shaft and a distal tip section containing diagnostic electrodes. The distal tip of deflectable catheters can be deflected into a curve by manipulating the hand piece.

Specific to the Inquiry™ Optima™, Optima™ Plus steerable electrophysiology catheters: The catheter incorporates both a deflectable shaft steering mechanism and a distal end with a

variable loop diameter, which allows selection of diameters within a specific range. The distal shaft may be deflected by pushing and pulling the thumb control and the distal loop diameter may be expanded or contracted by turning the rotating knob.

Specific to the AFocus™ steerable and the Inquiry™ fixed curve and steerable electrophysiology catheters: The catheters are flexible and insulated catheters constructed of noble metal electrodes and thermoplastic elastomer material. The control mechanism located in the handle at the proximal end of the catheter manipulates the tip of the steerable catheters. The distal tip on the AFocus™ catheter has been designed to expedite the collection of electrogram recordings of a circumferential area.

Indications for Use: Reprocessed Diagnostic Electrophysiology (EP) Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures. The reprocessed IBI AFocus™ Steerable and the Inquiry™ Optima™ catheters are to be used to map the atrial regions of the heart. The reprocessed Inquiry™ fixed curve and steerable catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.

Technological characteristics: The design, materials, and intended use of Reprocessed Electrophysiology Catheters are identical to the predicate devices. The mechanism of action of Reprocessed Electrophysiology Catheters is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of Electrophysiology Catheters includes removal of adherent visible soil and decontamination. Each individual Electrophysiology Catheter is tested for appropriate function of its components prior to packaging and labeling operations.

Performance data: Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed Electrophysiology Catheters. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed Electrophysiology Catheters perform as originally intended.

Conclusion:

Stryker Sustainability Solutions concludes that the modified devices (Reprocessed Electrophysiology Catheters) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Sustainability Solutions
c/o Amanda Babcock
Senior Regulatory Affairs Specialist
10232 South 51st Street.
Phoenix, AZ 85044

SEP 26 2011

Re: K112232
Trade/Device Name: Reprocessed Electrophysiology Catheters (See Enclosed List of Models)
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: 74 NLH
Dated: August 3, 2011
Received: August 4, 2011

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

List of Models Found SE:

Item Number	Description	French Size	Electrodes	Spacing	Curve
80001	IBI Inquiry Fixed Curve	6F	10	2-5-2mm	Josephson
80002	IBI Inquiry Fixed Curve	6F	10	2-5-2mm	Cournand
80003	IBI Inquiry Fixed Curve	6F	10	2-8-2mm	Special Curve
80051	IBI Inquiry Fixed Curve	5F	10	2mm	Josephson
80052	IBI Inquiry Fixed Curve	5F	10	2-5-2mm	Josephson
80055	IBI Inquiry Fixed Curve	5F	10	2-5-2mm	Cournand
80063	IBI Inquiry Fixed Curve	5F	10	2-8-2mm	Special Curve
80064	IBI Inquiry Fixed Curve	5F	10	2-8-2mm	Special Curve
80065	IBI Inquiry Fixed Curve	5F	10	2-5-2mm	Special Curve
80116	IBI Inquiry Fixed Curve	6F	10	2mm	Josephson
80131	IBI Inquiry Fixed Curve	4F	10	5mm	Cournand
80132	IBI Inquiry Fixed Curve	4F	10	2-5-2mm	Cournand
80133	IBI Inquiry Fixed Curve	4F	10	2mm	Josephson
80134	IBI Inquiry Fixed Curve	4F	10	5mm	Josephson
80135	IBI Inquiry Fixed Curve	4F	10	2-5-2mm	Josephson
80137	IBI Inquiry Fixed Curve	4F	10	5-50-5mm	Josephson 1
80138	IBI Inquiry Fixed Curve	4F	10	5-10-5mm	Josephson 1
80139	IBI Inquiry Fixed Curve	6F	10	2-8-2mm	Special Curve
80404	IBI Inquiry Fixed Curve	6F	4	2-2-2mm	Josephson
80405	IBI Inquiry Fixed Curve	6F	4	2-5-2mm	Josephson
80406	IBI Inquiry Fixed Curve	6F	4	5mm	Josephson
80407	IBI Inquiry Fixed Curve	6F	4	2mm	Cournand
80408	IBI Inquiry Fixed Curve	6F	4	2-5-2mm	Cournand
80409	IBI Inquiry Fixed Curve	6F	4	5mm	Cournand
80411	IBI Inquiry Fixed Curve	6F	4	2-5-2mm	Damato
80412	IBI Inquiry Fixed Curve	6F	4	5mm	Damato
80413	IBI Inquiry Fixed Curve	6F	4	10mm	Josephson
80414	IBI Inquiry Fixed Curve	6F	4	10mm	Cournand
80415	IBI Inquiry Fixed Curve	6F	4	10mm	Damato
80440	IBI Inquiry HIS Fixed Curve	5F	4	5mm	Cournand(HIS)
80451	IBI Inquiry Fixed Curve	5F	4	2mm	Josephson
80452	IBI Inquiry Fixed Curve	5F	4	2-5-2mm	Josephson
80453	IBI Inquiry Fixed Curve	5F	4	5mm	Josephson
80455	IBI Inquiry Fixed Curve	5F	4	2-5-2mm	Cournand
80456	IBI Inquiry Fixed Curve	5F	4	5mm	Cournand
80458	IBI Inquiry Fixed Curve	5F	4	2-5-2mm	Damato
80459	IBI Inquiry Fixed Curve	5F	4	5mm	Damato
80463	IBI Inquiry Fixed Curve	5F	4	10mm	Cournand
80464	IBI Inquiry Fixed Curve	4F	4	2mm	Cournand

Item Number	Description	French Size	Electrodes	Spacing	Curve
80465	IBI Inquiry Fixed Curve	4F	4	5mm	Cournand
80466	IBI Inquiry Fixed Curve	4F	4	2-5-2mm	Cournand
80467	IBI Inquiry Fixed Curve	4F	4	2mm	Josephson
80468	IBI Inquiry Fixed Curve	4F	4	5mm	Josephson
80469	IBI Inquiry Fixed Curve	4F	4	2-5-2mm	Josephson
80473	IBI Inquiry Fixed Curve	5F	4	5mm	Josephson
80476	IBI Inquiry Fixed Curve	5F	4	5mm	Cournand
80479	IBI Inquiry Fixed Curve	5F	4	5mm	Damato
80484	IBI Inquiry Fixed Curve	5F	4	5mm	Josephson 1
80485	IBI Inquiry Fixed Curve	4F	4	5mm	Josephson 1
80501	IBI Inquiry Fixed Curve	6F	5	2-5-2mm	Cournand
80508	IBI Inquiry Fixed Curve	6F	5	2-5-2mm	Josephson
80516	IBI Inquiry Fixed Curve	6F	4	2mm	Cournand
80517	IBI Inquiry Fixed Curve	6F	4	2-5-2mm	Josephson
80518	IBI Inquiry Fixed Curve	6F	4	10mm	Josephson 1
80519	IBI Inquiry Fixed Curve	6F	4	10mm	Damato
80520	IBI Inquiry Fixed Curve	6F	4	10mm	Cournand
80533	IBI Inquiry Fixed Curve	5F	10	2-8-2mm	Special Curve
80534	IBI Inquiry Fixed Curve	5F	10	5-30-5mm	Cournand
80535	IBI Inquiry Fixed Curve	4F	4	2-5-2mm	Josephson 1
80536	IBI Inquiry Fixed Curve	4F	4	5mm	Damato
80537	IBI Inquiry Fixed Curve	6F	4	10mm	Josephson
80544	IBI Inquiry Fixed Curve	5F	10	2-8-2mm	Cournand
80567	IBI Inquiry HIS Fixed Curve	4F	4	5mm	Cournand(HIS)
80602	IBI Inquiry Fixed Curve	6F	6	2-5-2mm	Josephson
80603	IBI Inquiry Fixed Curve	6F	6	5mm	Josephson
80604	IBI Inquiry Fixed Curve	6F	6	2mm	Cournand
80606	IBI Inquiry Fixed Curve	6F	6	5mm	Cournand
80627	IBI Inquiry Fixed Curve	5F	6	5mm	Josephson 1
80803	IBI Inquiry Fixed Curve	6F	8	5mm	Josephson
80804	IBI Inquiry Fixed Curve	6F	8	2mm	Cournand
80806	IBI Inquiry Fixed Curve	6F	8	5mm	Damato
80810	IBI Inquiry Fixed Curve	6F	8	5mm	Cournand
80820	IBI Inquiry HIS Fixed Curve	5F	8	20-5mm	Cournand(HIS)
80900	IBI Inquiry Fixed Curve	7F	14	3-3-3-3-3-3-70-3-3-3-3-3-3mm	Cournand
80945	IBI Inquiry Fixed Curve	7F	14	3(70)3mm	Cournand
81101	IBI Inquiry Steerable	6F	10	2mm	Medium 3.2cm
81102	IBI Inquiry Steerable	6F	10	2-5-2mm	Medium 3.2cm
81104	IBI Inquiry Steerable	6F	10	2-5-2mm	Large 4.1cm
81105	IBI Inquiry Steerable	6F	10	2-5-2mm	X-Large 5.0cm
81106	IBI Inquiry Steerable	6F	10	2-5-2mm	Far Reach
81107	IBI Inquiry Steerable	6F	10	5mm	Large 4.1cm

81108	IBI Inquiry Steerable	6F	10	2mm	Large 4.1cm
81109	IBI Inquiry Steerable	6F	10	2mm	Large 4.1cm
81110	IBI Inquiry H Steerable	6F	10	1-7-1mm	H
81120	IBI Inquiry H Steerable	7F	20	1-7-1mm	H
81121	IBI Inquiry H Steerable	7F	21	1-7-1mm	H-SC
Item Number	**Description**	**French Size**	**Electrodes**	**Spacing**	**Curve**
81124	IBI Inquiry H Steerable	7F	24	2-7-1mm	H
81125	IBI Inquiry H Steerable	7F	10	2-9-1mm	H
81126	IBI Inquiry H Steerable	7F	10	2-9-1mm	H-Large
81128	IBI Inquiry H Steerable	7F	21	5mm	H
81130	IBI Inquiry H Steerable	7F	20	1-9-1mm	H-Large
81131	IBI Inquiry H Steerable	7F	21	1-9-1mm	H-Large
81134	IBI Inquiry H Steerable	7F	24	2-9-1mm	H-Large
81136	IBI Inquiry H Steerable	7F	20	5mm	H-Large
81142	IBI Inquiry H Steerable	6F	6	2-7-2mm	H-Large
81150	IBI Inquiry H Steerable	7F	24	2-7-1mm	H-SCE
81171	IBI Inquiry Steerable	5F	10	2mm	Medium 3.2cm
81172	IBI Inquiry Steerable	5F	10	2-5-2mm	Medium 3.2cm
81174	IBI Inquiry Steerable	5F	10	2-5-2 mm	Large 4.1cm
81176	IBI Inquiry Steerable	5F	10	2-5-2 mm	Far Reach
81177	IBI Inquiry Steerable	5F	10	5mm	Large 4.1cm
81178	IBI Inquiry Steerable	5F	10	2mm	Large 4.1cm
81179	IBI Inquiry Steerable	5F	10	2mm	Extended Reach
81202	IBI Ten-Ten Duodecapolar	7F	20	2-10-2mm	XX Large 4.8cm
81203	IBI Inquiry Soft Tip Steerable	5F	10	2-5-2mm	Medium 3.2cm
81207	IBI Ten-Ten Duodecapolar	7F	20	5mm	Super Large 5.1cm
81209	IBI Ten-Ten Duodecapolar	7F	20	2-5-2mm	Super Large 5.1cm
81211	IBI Ten-Ten Duodecapolar	7F	20	2-20-2-25-2mm	Super Large 5.1cm
81223	IBI Inquiry Steerable	5F	10	2-50-3mm	X-Large 5.0cm
81224	IBI Inquiry Steerable	5F	10	2(30)3mm	Medium 3.2cm
81401	IBI Inquiry Steerable	6F	4	2mm	Small 2.7cm
81402	IBI Inquiry Steerable	6F	4	2-5-2mm	Medium 3.2cm
81403	IBI Inquiry Steerable	6F	4	5mm	Medium 3.2cm
81404	IBI Inquiry Steerable	6F	4	2-5-2mm	Large 4.1cm
81405	IBI Inquiry Steerable	6F	4	5mm	Large 4.1cm
81406	IBI Inquiry Steerable	6F	4	2-5-2mm	Extended Reach
81407	IBI Inquiry Steerable	6F	4	2-5-2mm	Far Reach
81412	IBI Inquiry Steerable	6F	4	2mm	Extended Reach
81417	IBI Inquiry Steerable	6F	4	5mm	X-Large 5.0cm
81418	IBI Inquiry Steerable	6F	4	2-5-2mm	X-Large 5.0cm
81471	IBI Inquiry Steerable	5F	4	5mm	Small 2.7cm
81472	IBI Inquiry Steerable	5F	4	2-5-2mm	Medium 3.2cm
81473	IBI Inquiry Steerable	5F	4	5mm	Medium 3.2cm
81474	IBI Inquiry Steerable	5F	4	2-5-2mm	Large 4.1cm
81475	IBI Inquiry Steerable	5F	4	5mm	Large 4.1cm

81478	IBI Inquiry Steerable	5F	4	2mm	Small 2.7cm
81479	IBI Inquiry Steerable	5F	4	2-5-2mm	Small 2.7cm
81483	IBI Inquiry HIS Steerable	5F	4	5mm	Extended (HIS)
81484	IBI Inquiry HIS Steerable	5F	4	5mm	L (EX-HIS)
81485	IBI Inquiry HIS Steerable	5F	4	5mm	Extended (EX-HIS)
81503	IBI Inquiry Bi-Directional	6F	4	5mm	Large 4.1cm
81504	IBI Inquiry Bi-Directional	6F	10	5mm	Medium 3.2cm
81511	IBI Inquiry Steerable	6F	6	2-5-2mm	Medium 3.2cm
Item Number	**Description**	**French Size**	**Electrodes**	**Spacing**	**Curve**
81520	IBI Inquiry Steerable	6F	10	2mm	X-Large 5.0cm
81521	IBI Inquiry Soft Tip Steerable	5F	5	5-170mm	Medium/Large
81524	IBI Inquiry Steerable	6F	10	2mm	Large 4.1cm
81530	IBI Inquiry Steerable	4F	10	2mm	Medium 3.2cm
81531	IBI Inquiry Steerable	4F	10	2-5-2mm	Medium 3.2cm
81532	IBI Inquiry Steerable	4F	10	2-5-2mm	Large 4.1cm
81534	IBI Inquiry Steerable	4F	10	5mm	Large 4.1cm
81536	IBI Inquiry Steerable	4F	10	2-5-2mm	Medium 3.2cm
81537	IBI Inquiry Steerable	4F	10	2-5-2mm	Medium 3.2cm
81540	IBI Inquiry Steerable	4F	4	2-5-2mm	Medium 3.2cm
81541	IBI Inquiry Steerable	4F	4	2mm	Medium 3.2cm
81542	IBI Inquiry Steerable	4F	4	5mm	Medium 3.2cm
81543	IBI Inquiry Steerable	4F	4	2-5-2mm	Large 4.1cm
81545	IBI Inquiry Steerable	4F	4	5mm	Large 4.1cm
81578	AFocus Steerable	5F	10	5mm	AF Curve (20mm Dia.)
81587	IBI A-Focus II Steerable	7F	20	1-2.5mm	20mm (A-Focus)
81589	IBI A-Focus II Steerable	7F	14	1-5-1mm	20mm (A-Focus)
81591	IBI A-Focus II Steerable	7F	14	1-3-1mm	15mm (A-Focus)
81594	IBI A-Focus II Steerable	7F	10	3.5mm	15mm (A-Focus)
81595	IBI A-Focus II Steerable	7F	10	5mm	20mm (A-Focus)
81596	IBI A-Focus II Steerable	7F	10	2-7mm	20mm (A-Focus)
81597	IBI A-Focus II Steerable	7F	10	2-11mm	25mm (A-Focus)
81599	IBI A-Focus II Steerable	7F	10	8mm	25mm (A-Focus)
81601	IBI Inquiry Steerable Curve	6F	6	5mm	Medium 3.2cm
81602	IBI Inquiry Steerable Curve	6F	6	5mm	Large 4.1cm
81603	IBI Inquiry Steerable Curve	6F	6	5mm	Extended Reach
81604	IBI Inquiry Steerable Curve	6F	6	5mm	Far Reach
81605	IBI Inquiry Steerable Curve	6F	6	5mm	X-Large 5.0cm
81659	IBI Optima Steerable Lasso	7F	20	1-4.5mm	25mm-15mm (Optima)
81670	IBI A-Focus I Steerable	5F	12	2-10mm	25mm (A-Focus)
81671	IBI A-Focus I Steerable	5F	14	2-9mm	30mm (A-Focus)
81672	IBI A-Focus II Steerable	5F	10	2-7-2mm	20mm (A-Focus)
81673	IBI A-Focus II Steerable	5F	10	5mm	20mm (A-Focus)
81674	IBI A-Focus I Steerable	5F	10	5mm	20mm (A-Focus)

81676	IBI A-Focus I Steerable	5F	10	3.5mm	15mm (A-Focus)
81680	IBI A-Focus II Steerable	5F	10	3.5mm	15mm (A-Focus)
81687	IBI Optima Steerable Lasso	7F	10	7mm	25mm-15mm (Optima)
81703	IBI Inquiry Soft Tip Steerable	5F	10	2-8-2mm	Medium/Large SC
81704	IBI Inquiry Soft Tip Steerable	5F	10	5mm	Medium/Large SC
81705	IBI Inquiry Soft Tip Steerable	5F	10	2-8-2mm	Medium SC
81706	IBI Inquiry Soft Tip Steerable	5F	10	5mm	Medium/Large XS
81711	IBI Inquiry HIS Steerable	5F	8	5-20-5mm	Extended (HIS)
81717	IBI Optima Steerable Lasso	7F	24	1-4.5mm	25mm-15mm (Optima)
81721	IBI Inquiry Soft Tip Steerable	5F	10	2-5-2mm	Medium SC
Item Number	**Description**	**French Size**	**Electrodes**	**Spacing**	**Curve**
81730	IBI Inquiry Soft Tip Steerable	5F	10	2-8-2mm	Medium/Large
81732	IBI Inquiry Soft Tip Steerable	5F	10	2-5-2mm	Medium 3.2cm
81733	IBI Inquiry Soft Tip Steerable	5F	10	2mm	Large 4.1cm
81734	IBI Inquiry Soft Tip Steerable	5F	10	2-5-2mm	Large 4.1cm
81735	IBI Inquiry Soft Tip Steerable	5F	10	5mm	Large 4.1cm
81738	IBI Inquiry Soft Tip Steerable	5F	10	1mm	Large 4.1cm
81742	IBI Inquiry Soft Tip Steerable	5F	4	2-5-2mm	Medium 3.2cm
81743	IBI Inquiry Soft Tip Steerable	5F	4	5mm	Medium 3.2cm
81745	IBI Inquiry Soft Tip Steerable	5F	4	2-5-2mm	Large 4.1cm
81750	IBI Inquiry Soft Tip Steerable	5F	10	2-5-2mm	Large 4.1cm
81751	IBI Inquiry Soft Tip Steerable	5F	8	2mm	Medium 3.2cm
81767	IBI Optima Steerable Lasso	7F	10	7mm	25mm-15mm (Optima)
81801	IBI Inquiry Steerable	6F	8	2mm	Medium 3.2cm
81802	IBI Inquiry Steerable	6F	8	2-5-2mm	Medium 3.2cm
81807	IBI Inquiry Steerable	6F	8	2mm	Large 4.1cm
81809	IBI Inquiry Steerable	6F	8	2-5-2mm	Large 4.1cm
81823	IBI Inquiry Soft Tip Steerable	6F	8	2mm	Medium 3.2cm
81871	IBI Inquiry Steerable	5F	8	2mm	Medium 3.2cm
81872	IBI Inquiry Steerable	5F	8	2-5-2mm	Medium 3.2cm
81873	IBI Inquiry Steerable	5F	8	5mm	Medium 3.2cm
81877	IBI Inquiry Steerable	5F	8	2mm	Large 4.1cm
81879	IBI Inquiry Steerable	5F	8	2-5-2 mm	Large 4.1cm
81901	IBI Ten-Ten Duodecapolar	7F	20	1-3-1mm	Medium 3.2cm
81902	IBI Ten-Ten Duodecapolar	7F	20	1-3-1mm	Large 4.1cm
81940	IBI Inquiry Soft Tip Steerable	6F	10	2mm	Medium 3.2cm
81943	IBI Inquiry Soft Tip Steerable	6F	10	2mm	Large 4.1cm
81945	IBI Inquiry Soft Tip Steerable	6F	10	2-5-2mm	Large 4.1cm
81947	IBI Inquiry Soft Tip Steerable	6F	10	5mm	Medium/Large
81951	IBI Inquiry Soft Tip Steerable	6F	4	5mm	Medium 3.2cm
81954	IBI Inquiry Soft Tip Steerable	6F	4	5mm	Large 4.1cm
87000	IBI Inquiry Steerable	7F	10	2.5-4-2.5-	Medium 3.2cm

				240mm	
87006	IBI Inquiry Steerable	6F	10	2-5-2mm	M/L
85931	Inquiry Diagnostic Connecting Cables	n/a	n/a	150 cm	n/a
85953	Inquiry Diagnostic Connecting Cables	n/a	n/a	150 cm	n/a
85954	Inquiry Diagnostic Connecting Cables	n/a	n/a	150 cm	n/a
85955	Inquiry Diagnostic Connecting Cables	n/a	n/a	150 cm	n/a
85930	Inquiry Diagnostic Connecting Cables	n/a	n/a	150 cm	n/a

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112232

Device Name: Reprocessed Electrophysiology Catheters

Indications For Use: Reprocessed Diagnostic Electrophysiology (EP) Catheters are intended for temporary intracardiac sensing, recording, stimulation, and electrophysiology mapping of cardiac structures. The reprocessed IBI AFocus™ Steerable and the Inquiry™ Optima™ catheters are to be used to map the atrial regions of the heart. The reprocessed Inquiry™ fixed curve and steerable catheters are commonly placed at the high right atrium, right ventricular apex, and HIS bundle.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112232